Docket No.: P0786.70000US05
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	John B. Sullivan et al.
Serial No.:	08/405,454
Filed:	March 15, 1995
For:	ANTIVENOM COMPOSITION CONTAINING FAB FRAGMENTS
Examiner:	Cherie M. Woodward
Art Unit:	1637

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Dated: June 24, 2011 Signature: /Paula J. Bramwell/ (Paula J. Bramwell)

INTERVIEW SUMMARY

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicants thanks the Examiner for the courtesy of the telephone interview with the undersigned on June 23, 2011. The Second Dart Declaration, the [First] Dart Declaration, the Second Russell Declaration, the First Russell Declaration, the Sullivan Declaration, and the Smith Declaration were all discussed during the interview. A second telephone interview was scheduled for June 28 at 2:00 p.m. Eastern time.

As discussed during the interview, claim 62 was not addressed in the Office Action mailed November 16, 2010. Claim 62 was introduced in the Amendment filed June 29, 2010. As indicated in that Amendment, claim 62 is supported by the application at, for example, page 5, lines 32-34 ("Furthermore, these antibody fragments can be products from monovalent, polyvalent and monoclonal sources.").

The Second Russell Declaration was also discussed regarding its ability to remove the Sullivan (1984) abstract as prior art. As discussed with the Examiner, there is no requirement that co-inventor and co-author John B. Sullivan submit a declaration similar to the declaration submitted by co-inventor and co-author Findlay E. Russell. Section 1.131 of the Rules and sections 715.01(c) and 2132.01of the MPEP use the singular "inventor" or "applicant" and do not require declarations from all inventors in the case of multiple inventors. Moreover, in *Ex Parte Magner*, 133 U.S.P.Q. 404 (Pat. Bd. App. 1961)(copy enclosed), the Board rejected an argument that all inventors needed to submit declarations to remove as prior art an article reporting their own work. In *Magner*, the application listed four inventors, and the cited reference listed three of the inventors as its authors. Those three co-inventors and co-authors submitted a declaration stating that the reference reported the work of the four inventors. The Board found that sufficient to remove the reference as prior art and rejected the Examiner's assertion that a declaration was needed from the fourth inventor as well. The declaration of the three inventors satisfied the requirement to explain the attribution of inventorship. *Id.* at 405.

Just as the declaration of all but one of the inventors was sufficient to remove their own work as prior art in *Magner*, the declaration of all but one of the inventors here is sufficient to remove their own work as prior art. As in *Magner*, "there is no reason to doubt the statement of [one of the] inventors as to the participation of the [other] inventor as this statement is of no consequence to [him]." *Id.* Accordingly, the Second Russell Declaration is sufficient to remove the Sullivan (1984) abstract as prior art.

Regarding the written description rejection, the undersigned stated that one skilled in the art would not have expected Fab and $F(ab)_2$ fragments to compete for the same sites and interfere with each other due to their different pharmacokinetics. The smaller, short half-life Fab fragments could rapidly reach venom toxins and neutralize them. Once the Fab fragments were cleared, the larger, longer half-life $F(ab)_2$ fragments could then bind any remaining venom toxins and neutralize them. Because each has a different time-course of action due to their different pharmacokinetics, Fab and $F(ab)_2$ fragments would not be expected to compete for the same sites and interfere with each other.

As evidence that Fab and $F(ab)_2$ fragments would not be expected to compete for the same sites and interfere with each other, Applicants refer to the Gutierrez article (Exhibit 19 to the Second Dart declaration). The Gutierrez article makes this very point when it suggests combining an antivenom containing Fab fragments with one containing $F(ab)_2$ fragments:

> Owing to this complexity, some antivenoms may have to include a mixture of Fab fragments and IgG or $F(ab)_2$ molecules. The former, having rapid equilibration and large volume of distribution, would allow rapid neutralization of small toxins in tissues, whereas the latter would assure repeated cycling in tissues and high plasma levels for a relatively extended time.

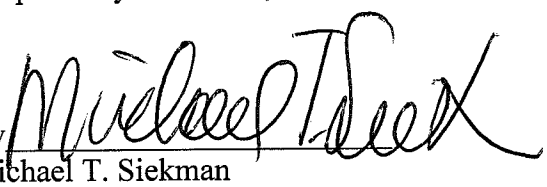
[Ex. 19 at p. 737.] Thus, rather than be expected to compete for binding sites and interfere with each other's action, after Applicants' invention, Fab fragments and $F(ab)_2$ fragments in an antivenom would be expected to complement each other by operating sequentially to neutralize venom toxins that have different kinetics.

As agreed with the Examiner, the undersigned will call the Examiner on June 28 at 2:00 p.m. Eastern time to discuss any remaining issues or concerns the Examiner may have.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 23/2825 under Docket No. P0786.70000US05 from which the undersigned is authorized to draw.

Dated: June 24, 2011

Respectfully submitted,

By 

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